

Applicant indicated in the parent application that the sequences disclosed in the parent applications might also contemplate fragments of the sequences disclosed. Applicant respectfully requests permission to submit evidence, in the form of serial number, line number and page number pointing to support for an earlier filing date at a later time.

Claims 1-6, 11-12, 14, 16-25 and 30-34 are rejected under 35 USC 112, first paragraph because the specification does not provide enablement for the various polynucleotides and vectors with 50% identity. In an effort to expedite prosecution, the claims have been amended and do not include "percent identity" language. In light of the above amendments and remarks, Applicant respectfully submits that the new claims are in a condition for allowance and requests that this rejection be withdrawn.

Claims 1-6, 11-12, 14 16-34 are rejected under 35 USC 101, because the claimed invention is not supported by a specific asserted utility or well established utility. The Examiner states that the specification teaches general utility for the invention, not a specific utility.

Furthermore, Applicant respectfully traverses this rejection. Applicant asserts that previously submitted arguments show a well-established utility and an asserted utility for the claimed invention. The specification teaches that the claimed gene products detected themselves in lung samples but not in non-lung RNA samples, thereby establishing that lung tissue is the host tissue of the claimed gene products. Applicant further clarifies that the detection of the claimed gene products OUTSIDE their host lung tissue, is diagnostically useful. Thus, presence of the claimed gene products outside normal host tissue serves as a diagnostic indicator that the host tissue is in a diseased state.

The polynucleotides are of interest when they are overexpressed in a tissue or body compartment where their normal occurrence is very low or non-existent. Such overexpression indicates that a disease has altered the polynucleotides so that they escape from their host tissue (in this case lung tissue) into other areas of the body. Thus, these polynucleotides are useful as markers for the detection of disease in lung tissue.

The court has consistently stated that claim language must be read in light of prior art and teachings of the specification. The standard is that the "definiteness of the language must be analyzed...in light of the teachings of the prior art and of the particular application disclosure as it would be interpreted by one possessing the ordinary level of skill in the pertinent art." *In re Moore*, 439 F.2d 1232, 169 USPQ 236 (CCPA 1971). The utility of gene products such as those claimed in the present invention are established in the art. Therefore, Applicant asserts that the examples and methods disclosed in the specification are useful for detecting, at the least, lung diseases that may be detected using gene markers and related gene marker technology.

Based on the above, it is clear that the presence or absence of gene products which are expressed in the body is of diagnostic significance for cancer in a manner consistent with the methods and products claimed in the claims as amended. Thus, the claimed polynucleotides of the present invention exhibit credible utility for several genres of tests well known in the art, whether direct or indirect in nature. Applicant respectfully submits that the claims as amended are now in a condition for allowance and requests that this rejection be withdrawn.

Claims 1-4 and 22-25 are rejected under 35 USC 112, second paragraph as indefinite. In light of the above amendments which remove "percent identity" language, Applicant respectfully submits that the new claims are in a condition for allowance and requests that this rejection be withdrawn.

Claims 1-6, 11-12, 14, 16-25 and 27-34 are rejected under 35 USC 112, first paragraph as containing subject matter which not described in the specification in such a way as to convey to one skilled in the art that the inventors were in possession of the claimed invention at the time of filing. In light of the above amendments which remove “percent identity” language, Applicant respectfully submits that the new claims are in a condition for allowance and requests that this rejection be withdrawn.

Claim 34 is rejected under 35 USC 102(b) as being anticipated by Kubota et al which teaches a polynucleotide with at least 50% identity to nucleotides 5-419 of SEQ ID NO:7. In light of the above amendments which remove “percent identity” language, Applicant respectfully submits that the new claims are in a condition for allowance and requests that this rejection be withdrawn.

Claim 14 is rejected under 35 USC 102(b) as being anticipated by Chen et al. Which teaches a polypeptide fragment having at least 50% identity to SEQ ID NO:7. In light of the above amendments which remove “percent identity” language, Applicant respectfully submits that the new claims are in a condition for allowance and requests that this rejection be withdrawn.

Claims 5-6, 16-21 and 27-29 are rejected under 35 USC 102(b) as being anticipated by Bonaldo et al. Which teaches a recombinant expression vector having a nucleic acid sequence with at least 50% identity with nucleotides 51-284 of SEQ ID NO:7. In light of the above amendments which remove “percent identity” language, Applicant respectfully submits that the new claims are in a condition for allowance and requests that this rejection be withdrawn.

Claim 11 is rejected under 35 USC 102(b) as being anticipated by Attie et al. In light of the above amendments which remove “percent identity” language, Applicant respectfully submits that the new claims are in a condition for allowance and requests that this rejection be withdrawn.

**CONCLUSION**

In view of the aforementioned amendments and remarks, Applicant respectfully submits that the above-referenced application is now in a condition for allowance and Applicant respectfully requests that the Examiner withdraw all outstanding objections and rejections and passes the application to allowance.

Respectfully submitted,  
P.A. Billing-Medel, *et al.*


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